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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,441	12/18/2001	Martin J. Jacobs	CP216	2296

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 02/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,441	JACOBS ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *88-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 17, 2004 has been entered.

Claims 1-87 have been canceled. New claims 88-98 have been added.

Claim Rejections - 35 USC § 102

Claims 88-94 are rejected under 35 U.S.C. 102(b) as being anticipated by RAMBERT et al (Neuropharmacology, 1994).

RAMBERT discloses oral or ip administration of an aqueous solution of modafinil to mice. The modafinil is solubilized using HP–β–cyclodextrin. The reference exemplifies dosages of 100 μg and 200 μg of modafinil in 10 μl of the injection solution. This corresponds to 10 mg/ml and 20 mg/ml, respectively.

Regarding the blood serum profile, claims 35-39, and 48 are written broadly with no requirement regarding the amount of composition to be administered in order to produce recited profile. These appear to be inherent characteristics of the composition. One of ordinary skill would expect that is more likely than not that the administration of some amount of the RAMBERT composition to some mammal would produce the blood serum profile of Fig. 1.

Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim Rejections - 35 USC § 103

Claims 88-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over RAMBERT et al (Neuropharmacology, 1994) in view of PITHA et al (Int. J. Pharm., 1986).

RAMBERT teaches as set forth above. The reference is silent regarding the properties recited in claims 89-92. Furthermore, Applicant previously (11/10/03) submitted a declaration stating that it was impossible to prepare a 10 mg/ml solution of modafinil in a 2% solution of 2–HP–β–cyclodextrin at room temperature. However, if the solution described by RAMBERT were not stable at room temperature (thus not suitable for use in clinical setting) the artisan would realize this upon attempting to use the composition as taught. It would be within the scope of the artisan to add more of the 2–HP–β–cyclodextrin in order to solubilize more modafinil.

PITHA teaches that 2–HP–β–cyclodextrin is highly soluble in water and is useful for solubilizing drugs with limited water solubility. See abstract; Fig. 1; and Table 1. The reference teaches that aqueous solutions comprising up to about 75% (w/w) of 2–HP–β–cyclodextrin can be prepared and that solubilities of some compounds in aqueous 2–HP–β–cyclodextrin (40-50% w/w) are up to three orders of magnitude higher than those in water. See page 79, right column.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the RAMBERT composition using a high concentration of 2–HP–β–cyclodextrin because PITHA had taught that this CD has very high water solubility and has very good solubilizing power for compounds having low water solubility. RAMBERT had already established that HP–β–cyclodextrin was useful for solubilizing modafinil, *per se*, so the artisan would reasonably expect success in preparing such a composition. One of ordinary skill would have been motivated to prepare a concentrated solution in order to minimize the volume of the solution necessary to solubilize the modafinil to be administered to a patient. In doing so, one of ordinary skill would reasonably expected to attain solutions having the physiological properties set forth in the claims.

Claims 88-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over RAMBERT et al (Neuropharmacology, 1994) in view of PITHA et al (Int. J. Pharm., 1986) and further in view of GREBOW et al (US 5,618,845).

RAMBERT teaches as set forth above. The reference is silent regarding the enantiomeric form of modafinil that is used.

PITHA teach as set forth above.

The references do not teach specific dosage amounts of modafinil.

GREBOW teaches that modafinil has utility for the treatment of a variety of disorders with the levorotatory form being the active enantiomer. See col 1. The reference further teaches the use of unit dosages of 100 mg, 200 mg, and 400 mg for humans. See col 4, lines 11-19 and col 2, lines 50-55.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare composition comprising an inclusion complex of modafinil and 2–HP–β–cyclodextrin in the recited dosages for the administration to patients treatment of the disorders taught by GREBOW. The artisan would be motivated to prepare such a composition for the increased solubility that the 2–HP–β–cyclodextrin confers upon modafinil. In the absence of unexpected results, one of ordinary skill would reasonably expect success in preparing said composition for the art disclosed utility of treating various neurological disorders.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
February 17, 2005